

## REMARKS

In an Office Action mailed June 17, 2003, the Examiner stated that Claims 9, 15, 16, and 20-47 are withdrawn from consideration as being drawn to a non-elected invention. Also, Claims 9, 17, and 19 are withdrawn from consideration as being drawn to a non-elected species. Claims 1-8, 10-14, and 18 are examined on the merits "to the extent they read on the elected invention and species."

The Examiner withdrew rejections under 35 U.S.C. §103 of claims relating to elected species NDGA for use in a method of controlling body fat, but rejected Claims 1-4, 10-14, and 18 under §103(a) over Verrando et al. and Miller et al. in view of Steinhart. The Examiner also objected to Claims 5-8, which recite an NDGA lipoxxygenase inhibitor, now stated to be free of the prior art. Each issue raised by the Examiner is considered separately below.

### Restriction and Election

Various claims remain restricted or unelected. The Examiner did not acknowledge applicants' concerns about the propriety of the restriction and elections. In particular, applicants should not be required to engage in serial prosecution of each lipoxxygenase inhibitor mentioned in the Markush group of Claim 3. In a prior response, and over the applicants' objections, applicants elected for prosecution a single lipoxxygenase inhibitor species (NDGA) that can be employed in the method of Claim 2. Having acknowledged that use of NDGA in such a method is free of the prior art, the Examiner has now *sui sponte* chosen a second species, indomethacin, without requesting election of another species or otherwise consulting the applicants. The basis for the Examiner's choice is not understood and clarification is respectfully requested. Separately, the Examiner has imposed a second level of election by limiting examination to a single animal species as well. Applicants do not understand the Examiner's approach to requiring election of a single animal species which, parenthetically, is not specifically claimed.

For reasons similar to those noted above, applicants question whether this approach is warranted or, indeed, permitted. Applicants again point out that broad independent method claims, not claims to lipoxxygenase inhibitors, are being examined and that prosecution can only be completed following robust prosecution of those independent method claims over their full scope. Applicants fear that limited-scope prosecution of the method claims will

force applicants to file and refile numerous applications and to maintain a family of closely related patents, without ever obtaining prosecution on the merits of the broad method claims.

Nevertheless, in the interest of advancing prosecution, applicants respond below to the rejections imposed, but again respectfully traverse the manner in which the claims are being examined in this case.

#### Rejections Under 35 U.S.C. §103

Applicants traverse the rejections under Section 103. At the outset, applicants question the propriety of examining Claim 18 as it stands, since this claim depends from Claim 17, which is itself withdrawn from consideration as being drawn to a non-elected species of animal suited for treatment in the method. Applicants respectfully request clarification on this point, and on the propriety of relying upon a withdrawn claim for dependency.

The Examiner alleges that Verrando teaches that indomethacin can enhance the maturity of adipose tissue and fat accumulation in mouse ob 17 pre-adipocytes. Applicants do not understand the relevance of this citation to the pending claims. First, Verrando relates to treatment of cells in culture with Clofenapate and indomethacin. The cited excerpts indicate that indomethacin can, indeed, accelerate conversion of ob 17 cells to adipose cells. Unfortunately, no relationship between this observation in cultured cells and the claimed method for controlling body fat in an animal is apparent. The Examiner offers no further explanation nor any basis for assuming or speculating that a skilled person reading Verrando would be motivated to use indomethacin as an agent for reducing lipoxxygenase activity in an animal or for having any expectation that this treatment would control body fat in the animal. The closest connection that the applicants can find is the mere mention of indomethacin and lipoprotein lipase in the same paper. However, the paper states that lipoprotein lipase is elevated in cultures that contain insulin and indomethacin, conditions that are not relevant to the pending claims.

The Examiner combines Verrando with Miller et al., a 1994 paper by the applicants and others. While the Examiner accurately summarizes Miller, the applicability to the pending claims is not understood. The Examiner is invited to refer to the applicants' general comments regarding body fat on pages 2 and 3 of the prior response. In view of those comments, the mere fact that CLA is known to prevent endotoxin-induced body fat and lean mass loss says nothing about its use in combination with a lipoxxygenase inhibitor as claimed


in Claims 10-14, and 18. The irrelevance of the Examiner's position is highlighted by the fourth paragraph on page 4 of the Office Action where it is stated that it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ both CLA and indomethacin together to prevent weight loss in endotoxin affected animals. The Examiner overlooks the fact that the claim makes no mention of endotoxin affected animals or of weight loss. Even if the Examiner is implicitly arguing that the art in some way suggests the invention in the limited context of endotoxin affected animals, no support is offered either for his reliance upon Verrando nor for its combination with Miller to arrive at the claimed invention. In response, the applicants wonder what it is about the two papers in combination that would lead a skilled person to the claimed method.

Finally, the Examiner draws into the combination a paper by Steinhart, a seven year old summary of early information relating to CLA that largely describes work done by the applicants and their co-workers at the University of Wisconsin-Madison. While the Examiner again accurately states the basic information present in Steinhart, Steinhart offers nothing that is not generally accepted knowledge in the field (such as the identity of various CLA isomers) and certainly proves no further link to use of a particular isomer of CLA in combination with a lipoxygenase inhibitor as claimed.

For all of these reasons, the rejections imposed against the claims cannot stand and should be withdrawn. Reconsideration is respectfully requested.

In view of the outstanding questions relating to the prosecution of this case, applicants have not yet placed Claims 5-8 into condition for allowance, but stand ready to do so when the other issues are addressed. If the Examiner is inclined to elect each lipoxygenase inhibitor *seriatum* for examination, applicants respectfully ask for the opportunity to discuss the proposed course of prosecution with the Examiner and his supervisor in a personal or telephonic interview.

Respectfully submitted,

  
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